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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,330	09/10/2004	John S Fisher	1139.26.CN	5329

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EXAMINER

DRYDEN, MATTHEW DUTTON

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/711,330	Applicant(s) FISHER ET AL.	
	Examiner Matthew D. Dryden	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This action is in response to applicant's amendment submitted on December 12, 2005.

Examiner acknowledges the amended claims in response to the first office action.

Drawings

Examiner acknowledges the corrected drawing, Figure 6.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,790,185.

Although the conflicting claims are not identical, they are not patentably distinct from

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each other because the claims recite every limitation that the applicant cites in the newly amended claims, and there is no imaging system that is provided in the claims of U.S. Patent No. 6,790,185 so these methods still read on the claims of the current application, and the methods are considered to be done blindly with no imaging means.

Regarding claim 3, these steps can be found in claims 1 and 4.

Regarding claim 4, see claims 1-4.

Regarding claim 5, see claims 1-8.

Regarding claim 6, see claim 9.

Regarding claim 7, see all of claim 1, specifically lines 42-43 (for markings), see lines 51-53 (for locking the plunger relative to the supporting structure), see around line 56 (for adapting a supporting structure to engage the coaxial needle).

Regarding claim 8, see claim 4.

Specification

The amendment filed December 12, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows: "a preselected length such as about" found on page 2 of the disclosure, line 12.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The step of subtracting a preselected length is much broader than what was originally disclosed by the applicant, originally the claim read as .5 centimeters and now that the applicant has changed the specification to read such as about half a centimeter the specification contains new matter and is much broader than originally disclosed.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Support for the step of dimensioning said sealant plug so that it has a length equal to or slightly greater than a length of said biopsy tract cannot be found in the specification and is viewed as new matter.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Support for the method step of marking a plunger with a

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plurality of measurement markings cannot be found in the specification, there is mention of graduation markings in centimeters being provided along the extent of the plunger but this is different than actually marking the plunger, the graduation markings as read by the examiner are already provided on the plunger.

Claim Objections

Claim 8 is objected to because of the following informalities: there are two periods at the end of claim 8, there should only be one period. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al (6544236) in view of Shaw. Cragg et al teaches the claimed invention and method except for the method comprising using a calibrated delivery system to position the sealant plug so that a trailing end of the positioned sealant plug is flush with the surface of the biopsied internal organ (see Columns 11-12, lines 15-32, for dimensioning see Column 12, lines 11-23). Shaw teaches it is known to provide a calibrated delivery system to position a sealant plug, so that the depth of the system and the depth of the distal end of the plug can be monitored without using a visual system (see Columns 6-11, lines 25-58). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Cragg et al to include a calibrated delivery system to position the sealant plug, as taught by

Shaw, so that the depth of the system and the depth of the distal end of the plug can be monitored without using a visual system.

Regarding claim 3, the device of Cragg et al as modified does not disclose an imaging means so it can be viewed as being done either blindly or without imaging means, for protruding from the surface of the biopsied internal organ see Column 12, lines 1-4.

Regarding claims 4, the device of Cragg et al as modified does not include any imaging means, and Cragg et al teaches it is known to position the plug to a preselected depth (the end of the biopsy tract) and provide a plug with a preselected length see Column 12, lines 11-22, through a needle so that the trailing end of the sealant plug is flush with or protrudes slightly beyond a surface of the biopsied organ, because Cragg et al teaches it is known to provide a sealant that fills the full biopsy tract of the organ, which would leave it flush with a surface of the biopsied internal organ. Also, Cragg et al teaches it is known to provide a variety of depths and positions for the sealant plug (see Columns 11-12, lines 40-4), for placing the plug or sealant flush with the end of the organ, (see column 11, lines 56-62).

Regarding claim 5, see rejection of claim 4 above, and also see column 11, lines 15-62 for the needle use.

Regarding claim 6, the assembly of both Shaw and Cragg et al are shown to be positioned external to a body of a patient (see Figure 6 in Cragg et al and Figures 2c-2e of Shaw).

Regarding claim 8, although the specific dimensions of zero centimeters to about one-half centimeter are not specifically taught by Cragg et al teaches it is known to provide a pledget or plug that may cross two or more anatomical structures such as an organ, surrounding tissue and facial layer, this can be a small amount as discussed by the applicant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Cragg et al with a plug or pledget that protrudes out of the biopsy tract of the biopsied internal organ by a small amount in the range of about zero centimeters to about one-half a centimeter for locating the site later on for analysis or for monitoring the progress of healing.

Response to Arguments

Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection. Because the claims were amended to overcome the art of Shaw and the applicant argues that Shaw does not teach a device for positioning in a biopsy tract, even though it is fairly evident that the device is capable of being used in a biopsy tract for positioning a plug. The Shaw reference is still pertinent to this application because it provides a measurement system for delivering a plug to prevent bleeding from the site of entry, Shaw with a combination of an instrument that positions a plug in a biopsy tract reads on the methods of the current application as applied above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew D. Dryden whose telephone number is (571) 272-6266. The examiner can normally be reached on Monday-Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MDD

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